9. 510(K) SUMMARY

MAY 3 0 2002

Submitted By:
Mark Bleyer
President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355

February 26, 2002

Device:

Trade Name:	SS Matrix™
Common/Usual Name:	Topical Wound Dressing
Proposed Classification Name:	Liquid bandage; 21 CFR 880.5090; Class I Product Code: 79KMF

Intended Use:
The SS Matrix™ is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds. The device is intended for one-time use.

Predicate Devices:
The SS Matrix™ is similar to predicate collagen-based wound dressings that are currently marketed for the management of wounds including the SIS Wound Dressing II (D.C. #K993948) manufactured by Cook Biotech Incorporated, the FIBRACOL* Plus Collagen Wound Dressing (D.C. #K982597) manufactured by Johnson & Johnson Medical, and the EZ Derm™ Biosynthetic Wound Dressing (D.C. #K935189) manufactured by Brennen Medical Incorporated.

Device Description:
The SS Matrix™ is primarily composed of porcine collagen that is supplied in sheet form in sizes ranging from 2 x 4 cm to 20 x 40 cm.

Substantial Equivalence:
The SS Matrix™ is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalence.

Discussion of Tests and Test Results:
The SS Matrix™ was subjected to a panel of tests to assess biocompatibility. The SS Matrix™ passed the requirements of all tests.

Conclusions Drawn from Tests:
This device is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2002

Mr. Mark Bleyer
President
Cook Biotech, Inc.
3055 Kent Avenue
West Lafayette, IN 47906

Re: K020732
Trade/Device Name: SS Matrix
Regulatory Class: unclassified
Product Code: KGN
Dated: March 5, 2002
Received: March 6, 2002

Dear Mr. Bleyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020732

Device Name: **SS Matrix™**

Indications For Use:

The SS Matrix is intended for the management of wounds including:

- **Partial and full-thickness wounds**
- **Pressure ulcers**
- **Venous ulcers**
- **Diabetic ulcers**
- **Chronic vascular ulcers**
- **Tunneled/undermined wounds**
- **Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)**
- **Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)**
- **Draining wounds.**

The device is intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020732

Prescription Use_____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)